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10/053,053

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Lee L. Swanstrom

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10/30/2007

APPLIED MEDICAL RESOURCES CORPORATION

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/053,053

Applicant(s)

SWANSTROM, LEE L.

Examiner

Timothy J. Neal

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-40, 42-53 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) 51-53 and 55-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-40, 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendments received on 3/22/2007.

Applicant's election without traverse of Group I claims 1-50 in the reply filed on 7/13/2007 is acknowledged. Claims 51-59 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6-12, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040).

Lenker discloses:

An apparatus for installing an implant in a hollow body organ having a vessel wall, including: means for transporting said implant into said hollow body organ (Fig 23B Item 348); a removable expansion assembly releasably engageable with said implant (Fig 23B), said removable expansion assembly includes a plurality of peripheral struts, said struts extending parallel to a longitudinal axis and spaced angularly thereabout (Fig 23B Item 342), said struts include like proximal ends, said proximal ends being free of mechanical connection (Fig 23B Item 342); means for dilating said expansion assembly and expanding a portion of said implant against said vessel wall (Fig 23B Item 342);

means for collapsing said expansion assembly and releasing said portion of said implant (Fig 23B Item 344).

6. The apparatus of claim 5, wherein said peripheral struts include like distal ends, said distal ends being secured together (Fig 23B Item 342).

7. The apparatus of claim 5, wherein said removable expansion assembly includes means for compressing said peripheral struts along said longitudinal axis to effect bowing of said peripheral struts radially outwardly from said longitudinal axis (Fig 23B Item 344).

8. The apparatus of claim 7, wherein said means for compressing includes an end cap, said end cap including means for releasably impinging on said proximal ends of said peripheral struts (Fig 23B Item 344).

9. The apparatus of claim 8, wherein said removable expansion assembly further includes a central strut extending parallel to said peripheral struts, said central strut being secured to said end cap (Fig 23B Item 350).

10. The apparatus of claim 9, wherein said means for compressing includes means for translating said central strut distally to urge said end cap to impinge on said proximal ends of said peripheral struts and compress said peripheral struts axially (Fig 23B Item

350).

11. The apparatus of claim 8, wherein said means for releasably impinging includes a recess formed in a distal surface of said end cap (Fig 23A Item 344).

12. The apparatus of claim 5, further including means for translating said peripheral struts distally along said longitudinal axis to move said proximal ends of said peripheral struts distally with respect to said means for fastening said portion of said implant to said vessel wall (Fig 23B Item 350).

Lenker discloses the invention substantially as claimed as stated above. Lenker does not disclose a means for fastening said portion of said implant to said vessel wall of said organ while said expansion assembly holds said portion against said vessel wall.

Mueller teaches means for fastening includes a fastener member adapted to be inserted within said implant (Fig 3a Item 10); further including at least one flexible tie connector extending from said fastener member (Fig 3 Item 12); further including needle means for containing said fastener member and flexible tie connector (Fig 3 Item 30), and means for driving said needle means through the exterior of said vessel wall to pierce said vessel wall and said implant (Fig 2 Item 52); said means for driving includes an endosurgical tool (Fig 2); further including push rod means for discharging said fastener member from said needle mean into the interior of said implant (Fig 2b Item 54), said at least one flexible tie connector including an external portion extending from

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said fastener member exteriorly of said vessel wall (Fig 3); further including means for applying tensile force to said external portion of said at least one flexible tie connector, whereby said implant and said vessel wall are clamped together between said fastener member and said external portion of said at least one flexible tie connector (Col 2 Line 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's implant apparatus to include Mueller's fastening means. Such a modification would secure the implant to the target wall.

Claims **2, 15, 20, 24, and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 1 above; and further in view of Hughes et al. (US 4,728,328).

Lenker and Mueller disclose the invention substantially as claimed as stated above. Lenker and Mueller do not disclose an implant comprises a tubular, sleeve-like component; wherein said tubular, sleeve-like component includes at least one cuff formed at a proximal end thereof; wherein said tubular, sleeve-like component includes an axial opening therethrough that is free of any mechanical structure; wherein said tubular, sleeve-like component includes at least one cuff formed at one end thereof; wherein said at least one cuff includes an end portion of said tubular, sleeve-like component folded retroflexively to impinge on the exterior of said component; further including at least one reinforcing band incorporated in said at least one cuff; wherein said at least one reinforcing band is resiliently biased to expand radially outwardly.

Hughes teaches an implant comprises a tubular, sleeve-like component; wherein said tubular, sleeve-like component includes at least one cuff formed at a proximal end thereof; wherein said tubular, sleeve-like component includes an axial opening therethrough that is free of any mechanical structure (Fig 1); wherein said tubular, sleeve-like component includes at least one cuff formed at one end thereof; wherein said at least one cuff includes an end portion of said tubular, sleeve-like component folded retroflexively to impinge on the exterior of said component (Fig 1). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's implant assembly to include Hughes' tubular sleeve. Such a modification would ensure long-term stability of the implant and reduce infection.

Claims 3, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claims 2 and 15 above, and further in view of Cox et al. (US 2003/0023301).

Lenker, Mueller, and Hughes disclose the invention substantially as claimed as stated above. They do not disclose a removable expansion assembly is disposed to translate concentrically within said tubular, sleeve-like component; a catheter assembly having a first tube; said first tube includes a lumen adapted to receive said tubular, sleeve-like component, said first tube having a diameter dimensioned so that the proximal end of said first tube engages said cuff in end-abutting relationship; wherein

said tubular, sleeve-like component is disposed in said lumen in a radially contracted state; wherein said catheter assembly includes a second tube disposed for axial translation concentrically within said first tube, said second tube having a proximal end dimensioned to engage the distal end of said tubular, sleeve-like component in end-abutting relationship.

Cox teaches a removable expansion assembly disposed to translate concentrically within said tubular, sleeve-like component (Fig 1); a catheter assembly having a first tube a catheter assembly having a first tube (Fig 1 Item 20); said first tube includes a lumen (Fig 1 Item 20) adapted to receive said tubular, sleeve-like component, said first tube having a diameter dimensioned so that the proximal end of said first tube engages said cuff in end-abutting relationship; wherein said tubular, sleeve-like component is disposed in said lumen in a radially contracted state (Fig 1); wherein said catheter assembly includes a second tube disposed for axial translation concentrically within said first tube (Fig 1 Item 11), said second tube having a proximal end dimensioned to engage the distal end of said tubular, sleeve-like component in end-abutting relationship. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Cox's catheter and tubes. Such a modification would protect the vessel from abrasion by the expansion member and force the implant out of the sleeve. The limitations following the phrases "adapted to" and "dimensioned to" are considered to be functional language and thus require nothing more than the ability to so perform.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 7 above, and further in view of Cox et al. (US 2003/0023301).

Lenker and Mueller disclose the invention substantially as claimed as stated above. Lenker and Mueller do not disclose a removable expansion assembly includes a confinement tube, said confinement tube having a lumen dimensioned to receive said peripheral struts in a non-expanded, collapsed state; confinement tube is translatable with respect to said peripheral struts to move said confinement tube selectively into concentric confinement of said peripheral struts.

Cox teaches a removable expansion assembly includes a confinement tube, said confinement tube having a lumen dimensioned to receive an expansion member in a non-expanded, collapsed state; confinement tube is translatable with respect to an expansion member to move said confinement tube selectively into concentric confinement of an expansion member (Paragraph 42). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's expansion assembly to include Cox's tube assembly. Such a modification would protect the vessel from abrasion by the expansion member.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al.

(US 4,728,328) as applied to claim 2 above, and further in view of Trescony et al. (US 5,653,745).

Lenker, Mueller, and Hughes disclose the invention substantially as claimed as stated above. They do not disclose a tubular sleeve-like component includes means for increased longitudinal stiffness; wherein said means for increased longitudinal stiffness includes a plurality of pleats extending longitudinally in said tubular, sleeve-like component.

Trescony teaches pleats extending longitudinally (Fig 1). Due to the substantially similar structure of the reference and the Applicant's implant, the Examiner considers the pleats to increase longitudinal stiffness. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Trescony's pleats. Such a modification would provide longitudinal support reducing stretching making the implant more durable.

Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of Tseng et al. (US 2004/0181278).

Lenker, Mueller, and Hughes disclose the invention substantially as claimed as stated above. They do not disclose a tubular sleeve-like component includes means for increased longitudinal stiffness; wherein said means for increased longitudinal stiffness

includes a plurality of stiffener struts secured longitudinally in said tubular, sleeve-like component.

Tseng teaches means for increased longitudinal stiffness; wherein said means for increased longitudinal stiffness includes a plurality of stiffener struts secured longitudinally in said tubular, sleeve-like component (Fig 7). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller, and Hughes' implant assembly to include Tseng's struts. Such a modification would provide longitudinal support reducing stretching making the implant more durable.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of Chevillon et al. (US 6,248,116).

Lenker, Mueller, and Hughes disclose the invention substantially as claimed as stated above. They do not disclose at least one reinforcing band incorporated in said at least one cuff; wherein said at least one reinforcing band is resiliently biased to expand radially outwardly.

Chevillon teaches at least one reinforcing band incorporated in said at least one cuff; wherein said at least one reinforcing band is resiliently biased to expand radially outwardly (Fig 1 Item 150). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker, Mueller,

and Hughes' implant assembly to include Chevillon's bands. Such a modification would reinforce the implant against the vessel wall.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) and Hughes et al. (US 4,728,328) as applied to claim 2 above, and further in view of White et al. (US 2006/0015176).

Lenker, Mueller, and Hughes disclose the invention substantially as claimed as stated above. They do not disclose an implant has a Y-configuration; wherein one branching end of said Y-configuration comprises an elongated tubular leg; wherein one branching end of said Y-configuration comprises a short connector leg.

White teaches an implant having a Y-configuration; wherein one branching end of said Y-configuration comprises an elongated tubular leg; wherein one branching end of said Y-configuration comprises a short connector leg (Fig 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify White's Y-configuration. Such a modification would be used for placement in a bifurcated blood vessel.

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Mueller et al. (US 4,705,040) as applied to claim 1 above, and further in view of Haber et al. (US 5,201,743).

Lenker and Mueller disclose the invention substantially as claimed as stated above. Lenker and Mueller do not disclose a means for winding including a torque-limiting mechanism and endosurgical tool.

Haber teaches means for applying tensile force include means for winding said at least one flexible tie connector about an winding axis; said means for winding includes a tool having a torque-limiting mechanism; said means for winding includes an endosurgical tool (Fig 6). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker and Mueller's implant assembly to include Haber's means for winding. Such a modification would secure the fastener to the tissue.

Claims 40 and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (6,350,278) in view of Cox et al. (US 2003/0023301).

Lenker discloses:

40. A removable expansion assembly for dilating a surgical implant within a hollow body organ, including: a plurality of peripheral struts (Fig 23B Item 342), said struts extending parallel to a longitudinal axis and spaced angularly thereabout and including like proximal ends, said proximal ends being free of mechanical connection (Fig 23B); means for urging said peripheral struts to expand radially outwardly from said longitudinal axis, whereby said surgical implant is dilated (Fig 23B).

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42. The removable expansion assembly of claim 40, wherein said peripheral struts include like distal ends, said distal ends being secured together (Fig 23A).

43. The removable expansion assembly of claim 40, wherein said means for urging said peripheral struts includes means for compressing said peripheral struts along said longitudinal axis to effect bowing of said peripheral struts radially outwardly from said longitudinal axis (Fig 23B).

44. The removable expansion assembly of claim 43, wherein said means for compressing includes an end cap, said end cap including means for releasably impinging on said proximal ends of said peripheral struts (Fig 23A and 23B).

45. The removable expansion assembly of claim 44, further including a central strut extending parallel to said peripheral struts, said central strut being secured to said end cap (Fig 23B Item 350).

46. The removable expansion assembly of claim 45, further including means for translating said central strut distally to urge said end cap to impinge on said proximal ends of said peripheral struts and compress said peripheral struts axially (Fig 23B).

47. The removable expansion assembly of claim 44, wherein said means for releasably impinging includes a recess formed in a distal surface of said end cap (Fig 23A).

48. The removable expansion assembly of claim 40, further including means for translating said peripheral struts distally along said longitudinal axis to move said proximal ends of said peripheral struts distally with respect to said end cap.

Lenker does not disclose wherein said implant comprises a tubular, sleeve-like component; wherein said removable expansion assembly is disposed to translate concentrically within said tubular, sleeve-like component, said plurality of peripheral struts being removably disposed within said surgical implant; further including a confinement tube, said confinement tube having a lumen dimensioned to receive said peripheral struts in a non-expanded, radially-collapsed state; wherein said confinement tube is translatable with respect to said peripheral struts to move said confinement tube selectively into concentric confinement of said peripheral struts.

Cox teaches an expansion member disposed within a surgical implant, a confinement tube having a lumen for receiving an expansion member in a non-expanded state, and a confinement tube translatable with respect to an expansion member (Paragraph 42). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Lenker's expansion assembly to include Cox's tube assembly. Such a modification would protect the vessel from abrasion by the expansion member. The Examiner notes that although the Lenker reference discloses the implant within the expansion member, it is common in the art as shown by the Cox reference to dispose the implant on the exterior of the expansion

member. Because the Lenker assembly is fully capable of expanding an implant, the Examiner considers the Cox reference to teach how this would be achieved.

Response to Arguments

Applicant's arguments filed 2/09/2007 have been fully considered but they are not persuasive.

The Applicant has argued that Lenker fails to disclose struts that are free of mechanical connection while remaining parallel to a longitudinal axis. The Examiner submits several responses to that argument. First, the claim does not specifically state the longitudinal axis the struts need to be parallel to, only that they are parallel to a longitudinal axis. As seen in figure 23B, the struts remain parallel to the longitudinal axis of Item 346 while free from Item 344. Secondly, the Examiner notes that the mechanical connection claimed does not specify what the struts must be free from. For example, are the struts free of mechanical connection from each other, free of mechanical connection from the rest of the device, free of mechanical connection from the device being delivered? The Examiner considers the struts to be free from mechanical connection from each other as seen in figures 23A and 23B. Finally, before the struts are fully expanded as shown in figure 23B, there is a transition stage from figure 23A. At the instant Item 344 is moved to release Items 342 are still substantially parallel to Item 348. For these reasons, the Examiner does not consider the current claim to overcome the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

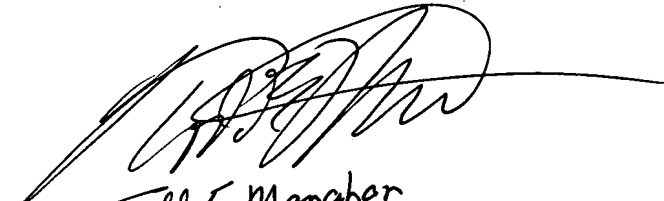
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



Todd E. Manahan
SPE 3731